

Dated: June 18, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Legislative Changes to Primary Care Loan Program Authorized Under Title VII of the Public Health Service Act

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: On March 23, 2010, President Obama signed into law the Affordable Care Act (ACA), Public Law 111-148. Section 5201 of the ACA changes the Primary Care Loan (PCL) program by: (1) Reducing the number of years for the primary health care service requirement; (2) lowering the interest rate for service default; and (3) eliminating the HHS requirement that parental financial information be submitted for independent students.

SUPPLEMENTARY INFORMATION: The PCL program was created through the Health Professions Education Extension Amendments of 1992 (Pub. L. 102-408), which established a new requirement for the use of the Health Professions Student Loan funds for allopathic and osteopathic schools. The PCL program strives to increase the number of primary care physicians by providing long-term, low interest rate loans to full-time students with financial need pursuing a degree in allopathic or osteopathic medicine. Below are details on how the ACA changes Section 723 of the Public Health Service Act (PHSA) regarding administration of the PCL program.

Primary Health Care Service Requirement

Under the PCL program, students were required to enter and complete a residency training program in primary health care and practice in primary health care until the PCL borrower's loan was repaid in full. The ACA change requires that for any new PCLs made on or after March 23, 2010, the PCL borrowers are to enter and complete residency training in primary health care and practice in primary health care for either 10 years (including the years spent in residency training) or through the date on which the loan is

repaid in full, whichever occurs first. (Section 5201(a)(1)(B) of the ACA).

Service Default Interest Rate

In the past, PCL borrowers who did not fulfill the service requirements and began practicing in a discipline or specialty other than primary health care were penalized by having their interest rate on the PCL recalculated at 18 percent. The ACA change requires that borrowers who receive a PCL on or after March 23, 2010, and fail to comply with the service requirements of the program will have their loans begin to accrue interest at an annual rate of 2 percent greater than the rate the student would pay if compliant. (Section 5201(a)(3) of the ACA.)

Parental Financial Information Requirement for Independent Students

Prior to enactment of the new law, independent students were required to provide parental financial information to the school's financial aid office so that the school could consider all financial resources available to the independent student for a PCL. The ACA change eliminates the HHS requirement for independent students to provide parental financial information to determine financial need. At its discretion, a school may still require parental financial information for independent students seeking a PCL. (Section 5201(b) of the ACA.) For this program, an independent student is a student who is at least 24 years of age and has been independent for a minimum of 3 years. Dependent students are still required to submit parental financial information.

The ACA changes to the PCL program will require a participating school to revise its PCL master promissory note for new loans made on or after March 23, 2010, to be consistent with the ACA.

Dated: June 21, 2010.

Mary K. Wakefield,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2009-M-0317, FDA-2009-M-0369, FDA-2009-M-0370, FDA-2009-M-0485, FDA-2009-M-0536, FDA-2009-M-0540]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993, 301-796-6570.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at <http://www.fda.gov>. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and